State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE

The agency identified below in box 1 provides notice of proposed rule change pursuant to *Utah Code* Sections 63-46a-4. Please address questions regarding information on this notice to the agency. The full text of all rule filings is published in the *Utah State Bulletin* unless excluded because of space constraints. The full text of all rule filings my also be inspected at the Division of Administrative Rules.

DAR file no:		Date filed:	
Utah Admin. Code ref. (R no.):	R156-17b	Time filed:	
Changed to Admin. Code Ref. (R no.):			

1.	Agency:	Commerce/Division of Occupational and Professional Licensing		
	Room no.:			
	Building:	Heber M. Wells Building		
	Street address 1:	160 East 300 South		
	Street address 2:			
	City, state, zip:	Salt Lake City UT 84111-2316		
	Mailing address 1:	PO Box 146741		
	Mailing address 2:			
	City, state, zip:	Salt Lake City UT 84114-6741		
	Contact person(s):			
	Name:	**Phone:**	**Fax:**	**E-mail:**
	Diana Baker	801-530-6179	801-530-6511	dbaker@utah.gov

(Interested persons may inspect this filing at the above address or at DAR between 8:00 a.m. and 5:00 p.m. on business days.)

2.	**Title of rule or section** (catchline)**:**
	Pharmacy Practice Act Rules
3.	**Type of notice:**
	New ___; Amendment XX; Repeal ___; Repeal and Reenact ___
4.	**Purpose of the rule or reason for the change:**
	The Division and State Board of Pharmacy have further reviewed the rule and need to make additional changes and clarifications as identified below.
5.	**This change is a response to comments from the Administrative Rules Review Committee.**
	Yes ___; No XX
6.	**Summary of the rule change:**

	Throughout the rule, amendments are being proposed to change the rule from plural to singular. Section 102-Definitions: The following definitions have been added "analytical laboratory", this definition was not included in the existing statute as a result of 2004 statute amendments and it needs to be defined; "central order entry", this is a new category of pharmacy that is off-site from the main pharmacy but is doing the business of the main pharmacy; "prescription files", this definition is a term that needs a clear definition; "refill", this definition is a term that is used frequently but needs a clear definition; "repackage", this definition is a term that needs a clear definition; "reverse distributor", this is a new category that has been previously licensed under a wholesale distributor until now; "wholesaler" and "wholesale distribution", these definitions require greater clarity. Also, the USP-NF in paragraph (25) was updated to the most current edition. Section 301-Pharmacy License Classifications: Added reverse distributing as a type of Class C pharmacy. A reverse distributor has been licensed as a wholesaler in the past, but needs it own category since wholesaler or distributor does not explain what their type of practice is. Also added durable medical equipment providers and central order entry pharmacies as a type of Class E pharmacies. Section 302-Licensure/Examinations: In paragraph (3)(b), added an equivalent certifying body in addition to the National Pharmacy Technician Certification Board and added that the certificate from the certifying body must exhibit a valid date and that the certification is active. Section 303:Licensure/Pharmacist by Endorsement: In paragraph (2)(a), changed the minimum of 2,000 hours of practice in two years to four years immediately preceding application in Utah to correct a discrepancy that existed between the governing statute and this rule. Section 304-Licensure/Education Requirements: Amendments made to eliminate the 15 hour semester requirement of pharmacy course work and allow the pharmacy student to become licensed as a pharmacy intern upon admission into a pharmacy program. Section 308-Renewal Cycle: In paragraph (3)(b), deleted the reference to the NAPLEX and MJPE examinations since these examinations cannot be taken until internship hours are completed. Section 402-Administrative Penalties: In paragraph (15) increased the fine amounts for paying rebates to practitioners or any other health care provider or entering into any agreement with a medical practitioner or any other person for the payment or acceptance of compensation for recommending the professional services of either party. Section 606-Operating Standards/Approved Preceptor: Amendment to clarify that interns on duty are at a 1:1 ratio and that students on educational rotation are at a 1:2 ratio with a pharmacist. Section 610-Operating Standards/Patient Counseling: In paragraph (4), added that records of an offer to counsel must be maintained for a period of five years and be available for inspection within 7-10 business days of a request for inspection.
7.	**Aggregate anticipated cost or savings to:**
	A) State budget:
	The Division will incur minimal costs of approximately $100 to reprint the rule once the proposed changes are made effective. Any costs incurred will be absorbed in the Division's current budget.
	B) Local government:
	The proposed amendments do not apply to local governments; therefore, no costs or savings are anticipated. The proposed amendments only apply to licensees and applicants for licensure in the various pharmacy license classifications.
	C) Other persons:
	The Division does not anticipate any cost or savings to other persons as a result of these rule amendments; except the amendment made in Section 402, which increased the administrative penalty for a defined misconduct, would only be applicable to licensees who engage in that misconduct. The Division is unable to determine how many licensees might engage in that misconduct and would therefore be subject to the increased fine amount.
8.	**Compliance costs for affected persons** ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization or any character other than an agency)**:**
	The Division does not anticipate any cost or savings as a result of these rule amendments; except the amendment made in Section 402, which increased the administrative penalty for a defined misconduct, would only be applicable to licensees who engage in that misconduct. The Division is unable to determine how many licensees might engage in that misconduct and would therefore be subject to the increased fine amount.
9.	**Comments by the department head on the fiscal impact the rule may have on businesses:**

	This proposed rule change makes clarifying amendments, including definitions, clarification of category subtitles, the acceptance of other testing companies, and other technical changes. No fiscal impact to businesses is anticipated as a result of these clarifying amendments. In addition, this filing increases the range for fines resulting from violations of the provision against paying rebates to health care providers. Those who are found to violate this provision could pay an increased fine of approximately $2,000 for each violation. Francine A. Giani, Executive Director
10.	**This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.** **State code or constitution citations** (required)**:**
	Section 58-17b-101, 58-37-1 and Subsections 58-17b-601(1), 58-1-106(1)(a) and 58-1-202(1)(a)
11.	**This rule adds, updates, or otherwise changes the following titles of materials incorporated by references** (a copy of materials incorporated by reference must be submitted to DAR; if none, leave blank)**:**
	Updates the USP-NF (United States Pharmacopeia-National Formulary) from the USP29-NF24, 2005 edition, through Supplement 1, dated April 1, 2006 to the USP30-NF25, 2007 edition, which is official from May 1, 2007 through Supplement 1, which is official from August 1, 2007.
12.	**The public may submit written or oral comments to the agency identified in box 1.** (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the *Utah State Bulletin*. See Section 63-46a-5 and Rule R15-1 for more information.)

A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy)**:**	05/15/2007
B) A public hearing (optional) will be held:	

on (mm/dd/yyyy)**:**	**at** (time)**:**	**At** (place)**:**

13.	**This rule change may become effective on** (mm/dd/yyyy)**:**	05/23/2007
	NOTE: The date above is the date on which this rule MAY become effective. It is *NOT* the effective date. After the date designated in Box 12(A) above, the agency *must* submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.	
14.	**Indexing information -- keywords** (maximum of four, in lower case, except for acronyms (e.g., "NASA") or proper nouns (e.g., "Medicaid")**:**	
	pharmacists	licensing
	pharmacies	
15.	**Attach an RTF document containing the text of this rule change** (filename)**:**	R156-17b.pro

To the agency: Information requested on this form is required by Sections 63-46a-4, 5, 6, and 10. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency head or designee, and title:	F. David Stanley, Director	**Date** (mm/dd/yyyy)**:**	04/02/2007

R156. Commerce, Occupational and Professional Licensing.
R156-17b. Pharmacy Practice Act Rule[~~s~~].
R156-17b-101. Title.

Th<u>is</u>[~~ese~~] rule[~~s are~~]<u>is</u> known as the "Pharmacy Practice Act Rule[~~s~~]".

R156-17b-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 17b, as used in Title 58, Chapters 1 and 17b or th<u>is</u>[~~ese~~] rule[~~s~~]:

(1) "ACPE" means the American Council on Pharmaceutical Education or Accreditation Council for Pharmacy Education.

<u>(2) "Analytical laboratory":</u>

<u>(a) means a facility in possession of prescription drugs for the purpose of analysis; and</u>

<u>(b) does not include a laboratory possessing prescription drugs used as standards and controls in performing drug monitoring or drug screening analysis if the prescription drugs are pre-diluted in a human or animal body fluid, human or animal body fluid components, organic solvents, or inorganic buffers at a concentration not exceeding one milligram per milliliter when labeled or otherwise designated as being for in-vitro diagnostic use.</u>

<u>(3) "Central Order Entry" means a pharmacy where functions are performed at the request of another pharmacy to perform processing functions such as dispensing, drug review, refill authorizations, and therapeutic interventions.</u>

([~~2~~]<u>4</u>) "Drugs", as used in th<u>is</u>[~~ese~~] rule[~~s~~], means drugs or devices.

([~~3~~]<u>5</u>) "Dispense", as defined in Subsection 58-17b-102(23), does not include transferring medications for a patient from a legally dispensed prescription for that particular patient into a daily or weekly drug container to facilitate the patient taking the correct medication.

([~~4~~]<u>6</u>) "Drug therapy management" means the review of a drug therapy regimen of a patient by one or more pharmacists for the purpose of evaluating and rendering advice to one or more practitioners regarding adjustment of the regimen.

([~~5~~]<u>7</u>) "High-risk, medium-risk, and low-risk drugs" refers to the risk to a patient's health from compounding sterile preparations, as referred to in USP-NF Chapter 797, for details of determining risk level.

([~~6~~]<u>8</u>) "Hospice facility pharmacy" means a pharmacy that supplies drugs to patients in a licensed healthcare facility for terminal patients.

([~~7~~]<u>9</u>) "Hospital clinic pharmacy" means a pharmacy that is located in an outpatient treatment area where a pharmacist or

pharmacy intern is compounding, admixing, or dispensing prescription drugs, and where:

(a) prescription drugs or devices are under the control of the pharmacist, or the facility for administration to patients of that facility;

(b) prescription drugs or devices are dispensed by the pharmacist or pharmacy intern; or

(c) prescription drugs are administered in accordance with the order of a practitioner by an employee or agent of the facility.

([~~8~~]10) "Legend drug" means any drug or device that has been determined to be unsafe for self-medication or any drug or device that bears or is required to bear the legend:

(a) "Caution: federal law prohibits dispensing without prescription";

(b) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(c) "Rx only".

([~~9~~]11) "Maintenance medications" means medications the patient takes on an ongoing basis.

([~~10~~]12) "MPJE" means the Multistate Jurisprudence Examination.

([~~11~~]13) "NABP" means the National Association of Boards of Pharmacy.

([~~12~~]14) "NAPLEX" means North American Pharmacy Licensing Examination.

([~~13~~]15) "Parenteral" means a method of drug delivery injected into body tissues but not via the gastrointestinal tract.

(16) "Prescription files" means all hard-copy and electronic prescriptions that includes pharmacist notes or technician notes, clarifications or information written or attached that is pertinent to the prescription.

([~~14~~]17) "PTCB" means the Pharmacy Technician Certification Board.

([~~15~~]18) "Qualified continuing education", as used in this[~~ese~~] rule[~~s~~], means continuing education that meets the standards set forth in Section R156-17b-309.

(19) "Refill" means to fill again.

(20) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding that completed by the pharmacist responsible for dispensing the product to a patient.

(21) "Reverse distributor" means a person or company that retrieves unusable or outdated drugs from a pharmacy or pharmacist for the purpose of removing those drugs from stock and destroying them.

([~~16~~]22) "Sterile products preparation facility" means any facility, or portion of the facility, that compounds sterile products using aseptic technique.

([~~17~~]23) "Unauthorized personnel" means any person who is not participating in the operational processes of the pharmacy who in some way would interrupt the natural flow of pharmaceutical care.

([~~18~~]24) "Unit dose" means the ordered amount of a drug in a dosage form prepared for a one-time administration to an individual and indicates the name, strength, lot number and expiration date for the drug.

([~~19~~]25) "Unprofessional conduct", as defined in Title 58, Chapters 1 and 17b, is further defined, in accordance with Subsection 58-1-203(1)(e), in Section R156-17b-502.

([~~20~~]26) "USP-NF" means the United States Pharmacopeia-National Formulary (USP [~~29~~]30-NF [~~24~~]25), 200[~~5~~]7 edition, which is official from [~~January 1, 2006~~]May 1, 2007 through Supplement 1, dated [~~April 1, 2006~~]August 1, 2007, which is hereby adopted and incorporated by reference.

(27) "Wholesaler" means a wholesale distributor who supplies or distributes drugs or medical devices that are restricted by federal law to sales based on the order of a physician to a person other than the consumer or patient. The term includes a person who derives, produces, prepares or repackages drugs or medical devices that are restricted by federal law to sales based on the order of a physician for resale.

(28) "Wholesale distribution" means the distribution of drugs to persons other than consumers or patients, but does not include:

(a) sales within a company;

(b) the purchase or other acquisition of a drug by a health care facility or a pharmacy that is a member of a purchasing organization;

(c) the sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug:

(i) between health care facilities or pharmacies that are under common control;

(ii) for emergency medical reasons; or

(iii) pursuant to a prescription;

(d) a transfer of drugs, in an amount not to exceed five percent of the total annual sales, by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(e) the distribution of drug samples by a representative of the manufacturer or distributor; or

(f) the sale, purchase or exchange of blood or blood components for transfusions.

R156-17b-103. Authority - Purpose.

This[~~ese~~] rule[~~s are~~]is adopted by the Division under the authority of Subsection 58-1-106(1)(a) to enable the Division to administer Title 58, Chapter 17b.

R156-17b-301. Pharmacy Licensure Classifications - Pharmacist-in-Charge Requirements.

In accordance with Subsection 58-17b-302(4), the classification of pharmacies holding licenses are clarified as:

(1) Class A pharmacy includes all retail operations located in Utah and requires a pharmacist-in-charge.

(2) Class B pharmacy includes an institutional pharmacy that provides services to a target population unique to the needs of the healthcare services required by the patient. All Class B pharmacies require a pharmacist-in-charge except for pharmaceutical administration facilities and methadone clinics. Examples of Class B pharmacies include:

(a) closed door;

(b) hospital clinic pharmacy;

(c) methadone clinics;

(d) nuclear;

(e) branch;

(f) hospice facility pharmacy;

(g) veterinarian pharmaceutical facility;

(h) pharmaceutical administration facility; and

(i) sterile product preparation facility.

(j) A retail pharmacy that prepares sterile products does not require a separate license as a Class B pharmacy.

(3) Class C pharmacy includes pharmacies located in Utah that are involved in:

(a) manufacturing;

(b) producing;

(c) wholesaling;[~~ and~~]

(d) distributing; and

(e) reverse distributing.

(4) Class D pharmacy includes pharmacies located outside the state of Utah. Class D pharmacies require a pharmacist-in-charge licensed in the state where the pharmacy is located and include Out-of-state mail order pharmacies. Facilities that have multiple locations must have licenses for each facility and every component part of a facility.

(5) Class E pharmacy includes those pharmacies that do not require a pharmacist-in-charge and include:

(a) medical gases providers;[~~ and~~]

(b) analytical laboratories

(c) durable medical equipment providers; and

(d) central order entry pharmacies.

(6) All pharmacy licenses will be converted to the appropriate classification by the Division as identified in Section 58-17b-302.

(7) Each Class A and each Class B pharmacy required to have a pharmacist-in-charge shall have one pharmacist-in-charge who is employed on a full-time basis as defined by the employer, who acts as a pharmacist-in-charge for one pharmacy. However, the pharmacist-in-charge may be the pharmacist-in-charge of more than one Class A pharmacy, if the additional Class A pharmacies are not open to provide pharmacy services simultaneously.

(8) The pharmacist-in-charge shall comply with the provisions of Section R156-17b-603.

R156-17b-302. Licensure - Examinations.

(1) In accordance with Subsection 58-17b-303(1)(h), the examinations that must be successfully passed by an applicant for licensure as a pharmacist are:

(a) the NAPLEX with a passing score as established by NABP; and

(b) the Multistate Pharmacy Jurisprudence Examination(MPJE) with a minimum passing score as established by NABP.

(2) In accordance with Subsection 58-17b-303(3)(j), an applicant applying by endorsement is required to pass the MPJE.

(3) In accordance with Subsection 58-17b-305(1)(g), the examinations which must be passed by an applicant applying for licensure as a pharmacy technician are:

(a) the Utah Pharmacy Technician Law and Rule Examination with a passing score of at least 75 and taken within six months prior to making application for licensure; and

(b) the National Pharmacy Technician Certification Board Examination, or equivalent certifying body, with a passing score as established by the [~~Pharmacy Technician Certification Board and taken within six months of completion of an approved education and training program~~]certifying body. The certificate must exhibit a valid date and that the certification is active.

R156-17b-303. Licensure - Pharmacist by Endorsement.

(1) In accordance with Subsections 58-17b-303(3) and 58-1-301(3), an applicant for licensure as a pharmacist by endorsement shall apply through the "Licensure Transfer Program" administered by NABP.

(2) An applicant for licensure as a pharmacist by endorsement does not need to provide evidence of intern hours if that applicant has:

(a) lawfully practiced as a licensed pharmacist a minimum

of 2000 hours in the [~~two~~]four years immediately preceding application in Utah;

(b) obtained sufficient continuing education credits required to maintain a license to practice pharmacy in the state of practice; and

(c) not had a pharmacist license suspended, revoked, canceled, surrendered, or otherwise restricted for any reason in any state for ten years prior to application in Utah, unless otherwise approved by the Division in collaboration with the Board.

R156-17b-304. Licensure - Education Requirements.

(1) In accordance with Subsections 58-17b-303(2) and 58-17b-304(7)(c), the credentialing agency recognized to provide certification and evaluate equivalency of a foreign educated pharmacy graduate is the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy Foundation, or an equivalent credentialing agency as approved by the Division.

(2) In accordance with Subsection 58-17b-304(6), [~~the preliminary education qualification for licensure as a pharmacy intern include~~]an applicant for a pharmacy intern license shall demonstrate that he meets one of the following education criteria:

(a) [~~a current pharmacy student who has completed at least 15 semester hours of pharmacy course work in a college or school of pharmacy accredited by the ACPE~~]current admission in a College of Pharmacy accredited by the ACPE by written verification from the Dean of the College; or

(b) a graduate [~~who has received a~~]degree from a school or college of pharmacy which is accredited by the ACPE; or

(c) a graduate degree from [~~of~~]a foreign pharmacy school [~~who has received~~]as established by a certificate of equivalency from an approved credentialing agency defined in Subsection (1).

(3) In accordance with Subsection 58-17b-305(1)(f), a pharmacy technician must complete an approved program of education and training that meets the following standards:

(a) The didactic training program must be approved by the Division in collaboration with the Board and must address, at a minimum, the following topics:

(i) legal aspects of pharmacy practice including federal and state laws and rules governing practice;

(ii) hygiene and aseptic techniques;

(iii) terminology, abbreviations and symbols;

(iv) pharmaceutical calculations;

(v) identification of drugs by trade and generic names, and therapeutic classifications;

(vi) filling of orders and prescriptions including packaging and labeling;

(vii) ordering, restocking, and maintaining drug inventory;

(viii) computer applications in the pharmacy; and

(ix) non-prescription products including cough and cold, nutritional, analgesics, allergy, diabetic testing supplies, first aid, ophthalmic, family planning, foot, feminine hygiene, gastrointestinal preparations, and pharmacy care over-the-counter drugs, except those over-the-counter drugs that are prescribed by a practitioner.

(b) This training program's curriculum and a copy of the final examination shall be submitted to the Division for approval by the Board prior to starting any training session with a pharmacy technician in training. The final examination must include questions covering each of the topics listed in Subsection (3)(a) above.

(c) Approval must be granted by the Division in collaboration with the Board before a student may start a program of study. An individual who completes a non-approved program is not eligible for licensure.

(d) The training program must require at least 180 hours of practical training supervised by a licensed pharmacist in good standing with the Division and must include written protocols and guidelines for the teaching pharmacist outlining the utilization and supervision of pharmacy technicians in training that includes:

(i) the specific manner in which supervision will be completed; and

(ii) an evaluative procedure to verify the accuracy and completeness of all acts, tasks and functions performed by the pharmacy technician in training.

(e) An individual must complete an approved training program and successfully pass the required examinations as listed in Subsection R156-17b-302(3) within one year from the date of the first day of the training program, unless otherwise approved by the Division in collaboration with the Board.

(i) An individual who has completed an approved program, but did not seek licensure within the one year time frame must complete a minimum of 180 hours of refresher practice in a pharmacy approved by the board if it has been more than six months since having exposure to pharmacy practice.

(ii) An individual who has been licensed as a pharmacy technician but allowed that license to expire for more than two years and wishes to renew that license must complete a minimum of 180 hours of refresher hours in an approved pharmacy under the direct supervision of a pharmacist.

(iii) An individual who has completed an approved program, but is awaiting the results of the required examinations may practice as a technician-in-training under the direct supervision of the pharmacist for a period not to exceed three months. If the individual fails the examinations, that individual can no longer work as at technician-in-training while waiting to retake the examinations. The individual shall work in the pharmacy only as supportive personnel.

(4) An applicant for licensure as a pharmacy technician is deemed to have met the qualification for licensure in Subsection 58-17b-305(f) if the applicant:

(a) is currently licensed and in good standing in another state and has not had any adverse action taken on that license;

(b) has engaged in the practice as a pharmacy technician for a minimum of 1,000 hours in that state within the past two years or equivalent experience as approved by the Division in collaboration with the Board; and

(c) has passed and maintained current the PTCB certification or a Board approved equivalent and passed the Utah law exam.

R156-17b-308. Renewal Cycle - Procedures.

(1) In accordance with Subsection 58-1-308(1), the renewal date for the two-year renewal cycle applicable to licensees under Title 58, Chapter 17b is established by rule in Section R156-1-308.

(2) Renewal procedures shall be in accordance with Section R156-1-308.

(3) An intern license may be extended upon the request of the licensee and approval by the Division under the following conditions:

(a) [~~have~~]the intern applied to the Division for a pharmacist license and to sit for the NAPLEX and MJPE examinations within three calendar months after obtaining full certification from the Foreign Pharmacy Graduate Equivalency Commission; or

(b) [~~have passed the NAPLEX and MJPE examinations but~~] the intern lacks the required number of internship hours for licensure.

(c) An individual must pass the NAPLEX and MJPE examinations and seek licensure as a pharmacist within six months of graduation and receipt of a degree from a school or college of pharmacy which is accredited by the ACPE. An internship license will not be extended beyond the six month time frame from graduation and receipt of a degree.

(4) The extended internship hours shall be under the direct supervision of a preceptor who meets the criteria

established in R156-17b-306(4).

R156-17b-402. Administrative Penalties.

In accordance with Subsection 58-17b-401(6) and Sections 58-17b-501 and 58-17b-502, unless otherwise ordered by the presiding officer, the following fine and citation schedule shall apply.

(1) Preventing or refusing to permit any authorized agent of the Division to conduct an inspection:

initial offense: $500 - $2,000

subsequent offense(s): $5,000

(2) Failing to deliver the license or permit or certificate to the Division upon demand:

initial offense: $100 - $1,000

subsequent offense(s): $500 - $2,000

(3) Using the title pharmacist, druggist, pharmacy intern, pharmacy technician or any other term having a similar meaning or any term having similar meaning when not licensed to do so:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(4) Conducting or transacting business under a name which contains as part of that name the words drugstore, pharmacy, drugs, medicine store, medicines, drug shop, apothecary, prescriptions or any other term having a similar meaning or in any manner advertising otherwise describing or referring to the place of the conducted business or profession when not licensed to do so:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(5) Buying, selling, causing to be sold, or offering for sale any drug or device which bears the inscription sample, not for resale, investigational purposes, or experimental use only or other similar words:

initial offense: $1,000 - $5,000

subsequent offense(s): $10,000

(6) Using to the licensee's own advantage or revealing to anyone other than the Division, Board or its authorized representatives, any information acquired under the authority of this chapter concerning any method or process which is a trade secret:

initial offense: $100 - $500

subsequent offense(s): $200 - $1,000

(7) Illegally procuring or attempting to procure any drug for the licensee or to have someone else procure or attempt to procure a drug:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(8) Filling, refilling or advertising the filling or refilling of prescription drugs when not licensed do to so:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(9) Requiring any employed pharmacist, pharmacy intern, pharmacy technician or authorized supportive personnel to engage in any conduct in violation of this chapter:

initial offense: $500 - $2,000

subsequent offense(s): $2,500 - $10,000

(10) Being in possession of a drug for an unlawful purpose:

initial offense: $500 - $1,000

subsequent offense(s): $1,500 - $5,000

(11) Dispensing a prescription drug to anyone who does not have a prescription from a practitioner or to anyone who is known or should be known as attempting to obtain drugs by fraud or misrepresentation:

initial offense: $500 - $2,000

subsequent offense(s): $2,500 - $10,000

(12) Selling, dispensing or otherwise trafficking in prescription drugs when not licensed to do so or when not exempted from licensure:

initial offense: $1,000 - $5,000

subsequent offense(s): $10,000

(13) Using a prescription drug or controlled substance for the licensee that was not lawfully prescribed for the licensee by a practitioner:

initial offense: $100 - $500

subsequent offense(s): $1,000 - $2,5000

(14) Willfully deceiving or attempting to deceive the Division, the Board or its authorized agents as to any relevant matter regarding compliance under this chapter:

initial offense: $500 - $2,000

subsequent offense(s): $2,500 - $10,000

(15) Paying rebates to practitioners or any other health care provider, or entering into any agreement with a medical practitioner or any other person for the payment or acceptance of compensation for recommending the professional services of either party:

initial offense: [~~$500 - $2,000~~]$2,500 - $5,000

subsequent offense(s): [~~$2,500~~]$5,500 - $10,000

(16) Misbranding or adulteration of any drug or device or the sale, distribution or dispensing of any outdated, misbranded, or adulterated drugs or devices:

initial offense: $1,000 - $5,000

subsequent offense(s): $10,000

(17) Accepting back and redistributing any unused drugs,

with the exception as provided in Section 58-17b-503:
initial offense: $1,000 - $5,000
subsequent offense(s): $10,000
(18) Violating Federal Title II, PL 91, Controlled Substances Act or Title 58, Chapter 37, Utah Controlled Substances Act, or rules and regulations adopted under either act:
initial offense: $500 - $2,000
subsequent offense(s): $2,500 - $10,000
(19) Failure to follow USP-NF Chapter 797 guidelines:
initial offense: $500 - $2,000
subsequent offense(s) $2,500 - $10,000
(20) Failure to follow USP-NF Chapter 795 guidelines:
initial offense: $250 - $500
subsequent offense(s): $500 - $750
(21) Administering without appropriate guidelines or lawful order:
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000
(22) Disclosing confidential patient information in violation of the provision of the Health Insurance Portability and Accountability Act of 1996 or other applicable law:
initial offense: $100 - $500
subsequent offense(s): $500 - $1,000
(23) Engaging in the practice of pharmacy without a licensed pharmacist designated as the pharmacist in charge:
initial offense: $100 - $500
subsequent offense(s): $2,000 - $10,000
(24) Failing to report to the Division any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency or court:
initial offense: $100 - $500
subsequent offense(s): $500 - $1,000
(25) Compounding a prescription drug for sale to another pharmaceutical facility:
initial offense: $100 - $500
subsequent offense(s): $500 - $1,000
(26) Preparing a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner:
initial offense: $500 - $1,000
subsequent offense(s): $2,500 - $5,000
(27) Violating any ethical code provision of the American Pharmaceutical Association Code of Ethics for Pharmacists, October 27, 1994:
initial offense: $250 - $500
subsequent offense(s): $2,000 - $10,000

(28) Failing to comply with the continuing education requirements set forth in this[~~ese~~] rule[~~s~~]:

initial offense: $100 - $500

subsequent offense(s): $500 - $1,000

(29) Failing to provide the Division with a current mailing address within 10 days following any change of address:

initial offense: $50 - $100

subsequent offense(s): $200 - $300

(30) Defaulting on a student loan:

initial offense: $100 - $200

subsequent offense(s): $200 - $500

(31) Failing to abide by all applicable federal and state law regarding the practice of pharmacy:

initial offense: $500 - $1,000

subsequent offense(s): $2,000 - $10,000

(32) Failing to comply with administrative inspections:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(33) Abandoning a pharmacy and/or leaving drugs accessible to the public:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(34) Failure to return or providing false information on a self-inspection report:

initial offense: $100 - $250

subsequent offense(s): $300 - $500

(35) Failure to pay an administrative fine:

Double the original penalty amount up to $10,000

(36) Any other conduct which constitutes unprofessional or unlawful conduct:

initial offense: $100 - $500

subsequent offense(s): $200 - $1,000

(37) Failure to maintain an appropriate ratio of personnel:

Pharmacist initial offense: $100 - $250

Pharmacist subsequent offense(s): $500 - $2,500

Pharmacy initial offense: $250 - $1,000

Pharmacy subsequent offense(s): $500 - $5,000

(38) Unauthorized people in the pharmacy:

Pharmacist initial offense: $50 - $100

Pharmacist subsequent offense(s): $250 - $500

Pharmacy initial offense: $250 - $500

Pharmacy subsequent offense(s): $1,000 - $2,000

(39) Failure to offer to counsel:

Pharmacy personnel initial offense: $500 - $2,500

Pharmacy personnel subsequent offense(s): $5,000 - $10,000

Pharmacy: $2,000 per occurrence

(40) Violations of the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division:

initial violation: $50 - $100

failure to comply within determined time: $250 - $500

subsequent violations: $250 - $500

failure to comply within established time: $750 - $1,000

(41) Practicing or attempting to practice as a pharmacist, pharmacist intern, or pharmacy technician or operating a pharmacy without a license:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(42) Impersonating a licensee or practicing under a false name:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(43) Knowingly employing an unlicensed person:

initial offense: $500 - $1,000

subsequent offense(s): $1,000 - $5,000

(44) Knowingly permitting the use of a license by another person:

initial offense: $500 - $1,000

subsequent offense(s): $1,000 - $5,000

(45) Obtaining a passing score, applying for or obtaining a license or otherwise dealing with the Division or Board through the use of fraud, forgery, intentional deception, misrepresentation, misstatement, or omission:

initial offense: $100 - $2,000

subsequent offense(s): $2,000 - $10,000

(46) Violating or aiding or abetting any other person to violate any statute, rule or order regulating pharmacy:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(47) Violating or aiding or abetting any other person to violate any generally accepted professional or ethical standard:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(48) Engaging in conduct that results in conviction of, or a plea of nolo contendere, or a plea of guilty or nolo contendere held in abeyance to a crime:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(49) Engaging in conduct that results in disciplinary action by any other jurisdiction or regulatory authority:

initial offense: $100 - $500

subsequent offense(s): $200 - $1,000

(50) Engaging in conduct, including the use of intoxicants

or drugs, to the extent that the conduct does or may impair the ability to safely engage in practice as a pharmacist, pharmacy intern or pharmacy technician:

initial offense: $100 - $500

subsequent offense(s): $200 - $1,000

(51) Practicing or attempting to practice as a pharmacist, pharmacy intern or pharmacy technician when physically or mentally unfit to do so:

initial offense: $100 - $500

subsequent offense(s): $200 - $1,000

(52) Practicing or attempting to practice as a pharmacist, pharmacy intern, or pharmacy technician through gross incompetence, gross negligence or a pattern of incompetency or negligence:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(53) Practicing or attempting to practice as a pharmacist, pharmacy intern or pharmacy technician by any form of action or communication which is false, misleading, deceptive or fraudulent:

initial offense: $100 - $500

subsequent offense(s): $200 - $1,000

(54) Practicing or attempting to practice as a pharmacist, pharmacy intern or pharmacy technician beyond the individual's scope of competency, abilities or education:

initial offense: $100 - $500

subsequent offense(s): $200 - $1,000

(55) Practicing or attempting to practice as a pharmacist, pharmacy intern or pharmacy technician beyond the scope of licensure:

initial offense: $100 - $500

subsequent offense(s): $200 - $1,000

(56) Verbally, physically or mentally abusing or exploiting any person through conduct connected with the licensee's practice:

initial offense: $100 - $1,000

subsequent offense(s): $500 - $2,000

(57) Failure to comply with the pharmacist-in-charge standards:

initial offense: $500 - $2,000

subsequent offense(s) $2,000 - $10,000

(58) Failure to resolve identified drug therapy management problems:

initial offense: $500 - $2,500

subsequent offense: $5,000 - $10,000

R156-17b-606. Operating Standards - Approved Preceptor.

In accordance with Subsection 58-17b-601(1), the operating standard for a pharmacist acting as a preceptor includes:

(1) supervising more than one intern; however, a preceptor may supervise only one intern actually on duty who is working for compensation in the practice of pharmacy at any one time. Interns who are doing educational, observational rotations can be supervised at two interns to one pharmacist ratio;

(2) maintaining adequate records to document the number of internship hours completed by the intern and evaluating the quality of the intern's performance during the internship;

(3) completing the preceptor section of a Utah Pharmacy Intern Experience Affidavit found in the application packet at the conclusion of the preceptor/intern relationship regardless of the time or circumstances under which that relationship is concluded; and

(4) being responsible for the intern's actions related to the practice of pharmacy while practicing as a pharmacy intern under supervision.

R156-17b-610. Operating Standards - Patient Counseling.

In accordance with Subsection 58-17b-601(1), guidelines for providing patient counseling established in Section 58-17b-613 include the following:

(1) Based upon the pharmacist's or pharmacy intern's professional judgment, patient counseling may be discussed to include the following elements:

(a) the name and description of the prescription drug;

(b) the dosage form, dose, route of administration and duration of drug therapy;

(c) intended use of the drug, when known, and expected action;

(d) special directions and precautions for preparation, administration and use by the patient;

(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescription refill information;

(i) action to be taken in the event of a missed dose;

(j) pharmacist comments relevant to the individual's drug therapy, including any other information specific to the patient or drug; and

(k) the date after which the prescription should not be taken or used, or the beyond use date.

(2) Patient counseling shall not be required for

inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drugs.

(3) A pharmacist shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation.

(4) The offer to counsel shall be documented and said documentation shall be available to the Division. <u>These records must be maintained for a period of five years and be available for inspection within 7-10 business days.</u>

(5) Counseling shall be:

(a) provided with each new prescription drug order, once yearly on maintenance medications, and if the pharmacist deems appropriate with prescription drug refills;

(b) provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent; and

(c) communicated verbally in person unless the patient or the patient's agent is not at the pharmacy or a specific communication barrier prohibits such verbal communication.

(6) Only a pharmacist or pharmacy intern may verbally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs.

(7) In addition to the requirements of Subsections (1) through (6) of this section, if a prescription drug order is delivered to the patient at the pharmacy, a filled prescription may not be delivered to a patient unless a pharmacist is in the pharmacy. However, an agent of the pharmacist may deliver a prescription drug order to the patient or the patient's agent if the pharmacist is absent for ten minutes or less and provided a record of the delivery is maintained and contains the following information:

(a) date of the delivery;

(b) unique identification number of the prescription drug order;

(c) patient's name;

(d) patient's phone number or the phone number of the person picking up the prescription; and

(e) signature of the person picking up the prescription.

(8) If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable:

(a) the information specified in Subsection (1) of this section shall be delivered with the dispensed prescription in writing;

(b) if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the

pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."; and

(c) written information provided in Subsection (8)(b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information.

R156-17b-614. Operating Standards - Operating Standards, Class A and B Pharmacy.

(1) In accordance with Subsection 58-17b-601(1), standards for the operations for a Class A and Class B pharmacy include:

(a) shall be well lighted, well ventilated, clean and sanitary;

(b) the dispensing area, if any, shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. This does not apply to clean rooms where sterile products are prepared. Clean rooms should not have sinks or floor drains that expose the area to an open sewer. All required equipment shall be clean and in good operating condition;

(c) be equipped to permit the orderly storage of prescription drugs and devices in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory;

(d) be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility;

(e) be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare; and

(f) be equipped with a security system to permit detection of entry at all times when the facility is closed.

(2) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator and freezer shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing.

(3) Facilities engaged in extensive compounding activities shall be required to maintain proper records and procedure

manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:

(a) must follow USP-NF Chapter 795, compounding of non-sterile preparations;

(b) may compound in anticipation of receiving prescriptions in limited amounts;

(c) bulk active ingredients must be component of FDA approved drugs listed in the approved drug products prepared by the Center for Drug Evaluation and Research of the FDA;

(d) compounding using drugs that are not part of a FDA approved drug listed in the approved drug products prepared by the Center for Drug Evaluation and Research of the FDA requires an investigational new drug application (IND). The IND approval shall be kept in the pharmacy for five years for inspection;

(e) a master worksheet sheet shall be developed and approved by a pharmacist for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once approved, a duplicate of the master worksheet sheet shall be used as the preparation worksheet sheet from which each batch is prepared and on which all documentation for that batch occurs. The master worksheet sheet shall contain at a minimum:

(i) the formula;

(ii) the components;

(iii) the compounding directions;

(iv) a sample label;

(v) evaluation and testing requirements;

(vi) sterilization methods, if applicable;

(vii) specific equipment used during preparation such as specific compounding device; and

(viii) storage requirements;

(f) a preparation worksheet sheet for each batch of sterile or non-sterile pharmaceuticals shall document the following:

(i) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;

(ii) manufacturer lot number for each component;

(iii) component manufacturer or suitable identifying number;

(iv) container specifications (e.g. syringe, pump cassette);

(v) unique lot or control number assigned to batch;

(vi) expiration date of batch prepared products;

(vii) date of preparation;

(viii) name, initials or electronic signature of the person or persons involved in the preparation;

(ix) names, initials or electronic signature of the

responsible pharmacist;

(x) end-product evaluation and testing specifications, if applicable; and

(xi) comparison of actual yield to anticipated yield, when appropriate;

(g) the label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum:

(i) the unique lot number assigned to the batch;

(ii) all solution and ingredient names, amounts, strengths and concentrations, when applicable;

(iii) quantity;

(iv) expiration date and time, when applicable;

(v) appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and

(vi) device-specific instructions, where appropriate;

(h) the expiration date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing;

(i) sources of drug stability information shall include the following:

(A) references can be found in Trissel's "Handbook on Injectable Drugs", 13th Edition, 2004;

(B) manufacturer recommendations; and

(C) reliable, published research;

(ii) when interpreting published drug stability information, the pharmacist shall consider all aspects of the final sterile product being prepared such as drug reservoir, drug concentration and storage conditions; and

(iii) methods for establishing expiration dates shall be documented; and

(i) there shall be a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities that follows the USP-NF Chapters 795 and 797 standards.

(4) The facility shall have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel:

(a) Title 58, Chapter 1, Division of Occupational and Professional Licensing Act'

(b) R156-1, General Rules of the Division of Occupational and Professional Licensing;

(c) Title 58, Chapter 17b, Pharmacy Practice Act;

(d) R156-17b, Utah Pharmacy Practice Act Rule[~~s~~];

(e) Title 58, Chapter 37, Utah Controlled Substances Act;

(f) R156-37, Utah Controlled Substances Act Rules;

(g) Code of Federal Regulations (CFR) 21, Food and Drugs, Part 1300 to end or equivalent such as the USP DI Drug Reference Guides;

(h) current FDA Approved Drug Products (orange book); and

(i) any other general drug references necessary to permit practice dictated by the usual and ordinary scope of practice to be conducted within that facility.

(5) The facility shall post the license of the facility and the license or a copy of the license of each pharmacist, pharmacy intern and pharmacy technician who is employed in the facility, but may not post the license of any pharmacist, pharmacy intern or pharmacy technician not actually employed in the facility.

(6) Facilities shall have a counseling area to allow for confidential patient counseling, where applicable.

(7) If the pharmacy is located within a larger facility such as a grocery or department store, and a licensed Utah pharmacist is not immediately available in the facility, the pharmacy shall not remain open to pharmacy patients and shall be locked in such a way as to bar entry to the public or any non-pharmacy personnel. All pharmacies located within a larger facility shall be locked and enclosed in such a way as to bar entry by the public or any non-pharmacy personnel when the pharmacy is closed.

(8) Only a licensed Utah pharmacist or authorized pharmacy personnel shall have access to the pharmacy when the pharmacy is closed.

(9) The facility shall maintain a permanent log of the initials or identification codes which identify each dispensing pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified; therefore identical initials or identification codes shall not be used.

(10) The pharmacy facility must maintain copy 3 of DEA order form (Form 222) which has been properly dated, initialed and filed and all copies of each unaccepted or defective order form and any attached statements or other documents.

(11) If applicable, a hard copy of the power of attorney authorizing a pharmacist to sign DEA order forms (Form 222) must be available to the Division whenever necessary.

(12) Pharmacists or other responsible individuals shall verify that the suppliers' invoices of legend drugs, including controlled substances, are listed on the invoices and were actually received by clearly recording their initials and the actual date of receipt of the controlled substances.

(13) The pharmacy facility must maintain a record of

suppliers' credit memos for controlled substances and legend drugs.

(14) A copy of inventories required under Section R156-17b-605 must be made available to the Division when requested.

(15) The pharmacy facility must maintain hard copy reports of surrender or destruction of controlled substances and legend drugs submitted to appropriate state or federal agencies.

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